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| APPLICATION NO.   | FILING DATE | FIRST NAMED INVENTOR    | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|-------------------------|---------------------|------------------|
| 09/214,679  | 12/30/1999  | WALTER BRIEDEN          | A32213-PCT          | 8348             |
| 21003   | 7590        | 03/04/2002              | EXAMINER            |                  |
| BAKER & BOTTS<br>30 ROCKEFELLER PLAZA<br>NEW YORK, NY 10112 |             |                         | RAO, MANJUNATH N    |                  |
| ART UNIT  |             | PAPER NUMBER            |                     |                  |
| 1652  |             | DATE MAILED: 03/04/2002 |                     | 44               |

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                             |                  |
|------------------------------|-----------------------------|------------------|
| <b>Office Action Summary</b> | Application No.             | Applicant(s)     |
|                              | 09/214,679                  | BRIEDEN ET AL.   |
|                              | Examiner<br>Manjunath N Rao | Art Unit<br>1652 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 27 December 2001.
- 2a) This action is **FINAL**.                            2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 22-40 is/are pending in the application.
  - 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 22-23, 25-26, 28-32, 35-40 is/are rejected.
- 7) Claim(s) 24,27,33 and 34 is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.
 

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.
 

If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All    b) Some \* c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
  - a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

#### Attachment(s)

|  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                             | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____                                    |

## **DETAILED ACTION**

New claims 22-40 are still at issue and are present for examination.

Applicants' arguments filed on 12-27-01, paper No. 13, have been fully considered and are deemed to be persuasive to overcome some of the rejections previously applied. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

### *Claim Objections*

Claims 23-24, 26-27 are objected to because of the following informalities: Claims 23-24 and 26-27 recite improper Markush groups. The word "or" preceding the final member of the group should be "and". Appropriate correction is required.

### *Claim Rejections - 35 USC § 112*

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 22, 25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 22 and 25 recite the phrase "capable of utilizing". The scope of the phrase is unclear to the Examiner. It is not clear to the Examiner whether the term "capable" means that the microorganism has the capacity to utilize propionamide under any or all conditions or only under certain conditions. If the microorganism has the capacity to utilize propionamide only under certain conditions then it is not clear to the Examiner as to what those conditions are. Deleting the phrase "capable of" would overcome this rejection.

Claim 28 and 32 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 28 and 32 recite the phrase “capable of hydrolyzing”. The scope of the phrase is unclear to the Examiner. It is not clear to the Examiner whether the term “capable” means that the enzyme has the capacity to hydrolyze propionamide under any or all conditions or only under certain conditions. If the enzyme has the capacity to hydrolyze propionamide only under certain conditions then it is not clear to the Examiner as to what those conditions are.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 22-23, 25-26, and claims 28—32, 35-40 which depend from claims 22-23 or 25-26 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for isolated microorganisms such as *K.oxytoca* PRS1, *K.Oxytoca* PRS1K17, *R. opacus* ID-622, *A.ramosus* ID620, *Bacillus* sp. ID-621, *K.planticula* ID-624, *K.pneumoniae* ID-625 or *Pseudomonas* sp. (DSM 11355) capable of utilizing (R)-3,3,3-trifluoro-2-hydroxy-2-methylpropionamide (THMP) as its sole source of nitrogen, a cell extract of these microorganism and a process of preparation of THMP using the amido hydrolase isolated from these microorganisms does not reasonably provide enablement for claiming any or all microorganisms (including variants and mutants) or any other strain or species or culture of the above

microorganisms with the characteristic property of utilizing THMP as sole nitrogen source nor any protein capable of converting THMP. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. See previous office action for rejection.

In response to the previous office action, applicants have traversed the above rejection arguing that the specification is indeed enabled and describes the methods for isolation of claimed microorganisms and also demonstrates working examples. Applicants also argue that while some experimentation may be necessary to isolate the microorganism, such experimentation cannot be undue. Examiner respectfully disagrees. Applicants are claiming “any or all microorganisms”. The term “microorganisms” is very broad and includes thousands of bacterial species and strains, fungi, cyanobacteria, archaebacteria, and yeasts. Furthermore applicants also include whole genus of microorganisms which comprise thousands of species and strains. While Examiner also agrees that some experimentation may be necessary for isolation of specific microorganisms within a small group, experimentation to identify such microorganisms from a group consisting hundreds and thousands of microorganisms would constitute undue burden to one skilled in the art and even though applicants have shown the isolation of few specific strains they are not representative of the entire world of “microorganisms”. As stated in the previous office action the specification does not support the broad scope of the claims which encompass all microorganisms with the above characteristics because the specification does not establish: (A) that the mechanism involved (enzymatic pathway) in the use of THMP as sole source of nitrogen is universal in all microorganisms and; (B) the specification provides

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insufficient guidance as to which of the essentially infinite possible choices is likely to be successful. Therefore the above rejection is maintained.

Claims 22-23, 25-26, and claims 28—32, 35-40 which depend from claims 22-23 or 25-26 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. See previous office action for rejection.

In response to the previous office action applicants have traversed the above rejection and argue that the specification does describe the claimed microorganisms as only those that are capable of utilizing propionamide as the sole nitrogen source and that they have disclosed eight different microorganisms having the above characteristics. Applicants argue that they have not provided one but eight different microorganisms and hence the invention is fully described. Examiner respectfully disagrees. Applicants are not claiming just eight of the microorganisms that they have isolated but all microorganisms. Above claims are rejected because applicants are claiming an extremely large group of microorganisms and have not described a representative number of those microorganisms. The eight microorganisms described does not form a representative group of all hundreds and thousands of microorganisms which includes all bacteria, fungi, algae (cyanobacteria) and yeasts. Therefore the above rejection is maintained.

Claim 28 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled

in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 28 is directed to methods of using any polypeptide with amidohydrolase activity which can hydrolyze THMP. Claim 28 is rejected under this section of 35 USC 112 because the claim is directed to a genus of methods utilizing polypeptides including modified polypeptide sequences, modified by at least one of deletion, addition, insertion and substitution of an amino acid residue that have not been disclosed in the specification. No description has been provided of all the polypeptides including the modified polypeptide sequences encompassed by the claim. No information, beyond the characterization of SEQ ID NO:2 has been provided by applicants which would indicate that they had possession of the claimed genus of modified polypeptides. The specification does not contain any disclosure of the structure of all the polypeptide sequences with the above activity or derived from SEQ ID NO:2, including fragments and variants within the scope of the claimed genus. The genus of polypeptides claimed is a large variable genus including peptides which can have a wide variety of structures. Therefore many structurally unrelated polypeptides are encompassed within the scope of these claims. The specification discloses only a single species of the claimed genus which is insufficient to put one of skill in the art in possession of the attributes and features of all species within the claimed genus. Therefore, one skilled in the art cannot reasonably conclude that applicant had possession of the claimed invention at the time the instant application was filed.

Applicant is referred to the revised guidelines concerning compliance with the written description requirement of U.S.C. 112, first paragraph, published in the Official Gazette and also available at [www.uspto.gov](http://www.uspto.gov).

*Allowable Subject Matter*

Claims 24, 27, 33, 34 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

*Conclusion*

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Manjunath Rao whose telephone number is (703) 306-5681. The Examiner can normally be reached on M-F from 6:30 a.m. to 3:00 p.m. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, P.Achutamurthy, can be

reached on (703) 308-3804. The fax number for Official Papers to Technology Center 1600 is (703) 305-3014. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.



REBECCA E. PROUTY  
PRIMARY EXAMINER  
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1600

Manjunath N. Rao. Ph.D.  
March 1, 2002